NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN, L.P., et al.,	:	
Plaintiffs,	:	
v.	:	CIVIL ACTION NO. 07-1515 (JAP)
BARR LABORATORIES, INC., et al,	:	
	:	**OPINION**
Defendants.	:	

On March 30, 2007, Plaintiffs Janssen, L.P., Janssen Pharmaceutica N.V., and Ortho-McNeil Neurologics, Inc. (collectively, "Plaintiffs") filed a Complaint for patent infringement. The Complaint includes an allegation that Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Defendants") willfully infringed the patent owned by Plaintiffs by filing with the Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") and "paragraph IV certifications." Presently before the Court is Defendants' motion for a judgment on the pleadings as to Plaintiffs' willful infringement claim, as it relates to that ANDA filing, pursuant to Federal Rule of Civil Procedure 12(c) and, in the alternative, to bifurcate that claim and stay discovery. Plaintiffs oppose the motion. For the reasons set forth herein, the Court grants Defendants' motion and dismisses Plaintiffs' willful infringement claim.

I. BACKGROUND

A. The Hatch-Waxman Act

Plaintiffs brought this cause of action under the Drug Price Competition and Patent Term

Restoration Act of 1984, more commonly referred to as the Hatch-Waxman Act ("the Act"), which modified the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 ("FDCA"). 21 U.S.C. §§ 355, 360c; 35 U.S.C. §§ 156, 271, 282; *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002). In passing that Act, Congress sought to "balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Id.* at 1371.

Specifically, the Hatch-Waxman Act permits a manufacturer seeking to market a generic equivalent of a previously FDA-approved drug to file an ANDA, rather than a more lengthy New Drug Application ("NDA"), to obtain approval for their generic drug. 21 U.S.C. § 355(j). Under this system, a generic-drug manufacturer "may rely on safety and efficacy studies previously submitted by the pioneer manufacturer by submitting information showing the generic drug's bioequivalence with the previously approved drug product." *Andrx*, *supra*, 276 F.3d at 1371; 21 U.S.C. § 355(j)(2)(A). As part of the application process, an ANDA applicant also must provide a certification as to each patent covering the previously-approved drug. 21 U.S.C. § 355(j)(2)(A)(vii). An applicant files a "paragraph IV certification" if the applicant believes "to the best of his knowledge . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]" 21 U.S.C. § 355(j)(2)(A)(vii)(IV). "Applicants use [p]aragraph IV [c]ertifications to essentially challenge the validity of the brand-name drug manufacturers' patents." *Celgene Corp. v. Teva Pharm. USA, Inc.*, 412 F. Supp. 2d 439, 441 (D.N.J. 2006).

If an ANDA applicant files a paragraph IV certification, the applicant must give notice of that certification to "each owner of the patent that is the subject of the certification . . . and . . .

the holder of the approved [NDA] . . . ." 21 U.S.C. § 355(j)(2)(B)(iii). Upon receipt of that notice, a patent-holder has a forty-five-day period in which to bring an action for patent infringement before the FDA approves the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If a patent-holder does file such a suit, then the FDA will not approve the ANDA until the court rules that the patent is not infringed or until the expiration of thirty months, beginning on the date the patent-holder received notice of the ANDA, whichever occurs first. 21 U.S.C. § 355(j)(5)(B)(iii).

A claim for patent infringement is generally made against "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor[.]" 35 U.S.C. § 271(a). Because a generic-drug manufacturer has not yet placed the generic drug into the market when it files an ANDA application, a patent-holder cannot make a claim for patent infringement under section 271(a). To circumvent that bar, the Hatch-Waxman Act "provides a jurisdictional basis for an infringement action against the applicant where it seeks approval to market a patented product before the expiration of the patent." *Celgene*, *supra*, 412 F. Supp. 2d at 441. *See also Eli Lilly and Co. v. Medtonic, Inc.*, 496 U.S. 661, 678 (1990) (noting that "an act of infringement had to be created for these ANDA . . . proceedings[and t]hat is what is achieved by § 271(e)(2)"). Thereby, Congress created "a highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *Eli Lilly*, *supra*, 496 U.S. at 678. Thus, through 35 U.S.C. § 271(e)(2) , Congress extended the Court's jurisdiction over a hypothetical issue: if

the defendant's proposed generic drug was on the market, would it infringe on the plaintiff's patent. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1366 (Fed. Cir. 2003). It is on this hypothetical issue that Plaintiffs base their Complaint.

B. Plaintiffs' Complaint

Plaintiffs are in the business of manufacturing and producing RAZADYNE ER®, a brand-name drug used to treat "mild to moderate dementia of the Alzheimer's type." (Cmplt. ¶ 17). To conduct their business, Plaintiffs are the holders of approved NDA No. 21-615, which covers controlled release compositions of galantamine hydrobromide as found in RAZADYNE ER®. (Cmplt. ¶ 17). Plaintiffs also own Patent Number 7,160,559 ("the '559 patent"), covering an approved use of the drug product that is the subject of the NDA. (Cmplt. ¶ 17, 20). Defendants are generic-drug manufacturers, seeking to produce and market a generic drug that is bioequivalent to Plaintiffs' RAZADYNE ER®. On May 19, 2006, Defendants filed with the FDA ANDA No. 78-189 and paragraph IV certifications, averring that Defendants intend "to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide extended-release capsules before the expiration of [Plaintiffs'] patents [relating to] NDA No. 21-615." (Cmplt. ¶ 22).

After having received notice of the paragraph IV certifications relating to the '559 patent, Plaintiffs filed their one-count Complaint, alleging that "[t]he conditions of use for which [Defendants] seek[] approval in [their] ANDA No. 78-189 fall within one or more of the claims of the '559 patent." (Cmplt. ¶ 31). For purposes of this motion, the Court focuses on two specific allegations found in paragraphs 32 and 35. Paragraph 32 states that "[Defendants are] liable for infringement of the '559 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of [their]

filing ANDA No. 78-189 with a paragraph IV certification seeking FDA approval of ANDA No. 78-189 prior to expiration of the '559 patent. . . ." (Cmplt. ¶ 32). Significantly, Plaintiffs also allege in paragraph 35 that "[Defendants'] infringement of the '559 patent has been, and continues to be, willful." (Cmplt. ¶ 35). After setting forth those allegations, Plaintiffs seek the Court to enter a "judgment that [Defendants have] infringed the '559 patent under 35 U.S.C. § 271(e)(2)(A), and that such infringement is willful." (Cmplt. ¶ A).

Challenging that allegation of willful infringement, Defendants now move pursuant to Federal Rule of Civil Procedure 12(c) for a judgment on the pleadings. Defendants argue that Plaintiffs cannot sustain, as a matter of law, their willful infringement claim raised in paragraph 35 of the Complaint because that claim is based solely on the filing of an ANDA and paragraph IV certification. Plaintiffs oppose the motion, contending that they may assert, and later develop during discovery, a willful infringement claim.

II. DISCUSSION

A. Standard of Review under Federal Rule of Civil Procedure 12(c)

Federal Rule of Civil Procedure 12(c) permits a party to "move for judgment on the pleadings." Fed. R. Civ. P. 12(c). "The standard for deciding a motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is identical to that under Rule 12(b)(6)." *Celgene*, *supra*, 412 F. Supp. 2d at 443. Accordingly, the Court must construe as true all allegations in the Complaint. *Robb v. Philadelphia*, 733 F.2d 286, 290 (3d Cir. 1984). The Court will grant a motion under Rule 12(c) if, considering the allegations in the light most favorable to Plaintiff, "it appears beyond doubt that no relief could be granted under any set of facts which could be proved consistent with the allegations[.]" *Celgene*, *supra*, 412 F. Supp. 2d

at 443. Therefore, "[t]he narrow issue before the Court . . . is whether or not [D]efendant[s] could be found to have engaged in an act of 'willful infringement' in this Hatch-Waxman Act case." *Ibid.*

B. Analysis

As discussed above, the Hatch-Waxman Act creates the opportunity for an artificial "act of infringement" to occur upon the submission of "an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent[.]" 35 U.S.C. § 271(e)(2)(A); *Eli Lilly*, *supra*, 496 U.S. at 678. "Thus, under the terms of the Act, an ANDA filer may infringe without even engaging in any actual commercial activities[; t]he mere act of filing an ANDA constitutes infringement." *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1346 (Fed Cir. 2000).

Based on the artificial nature of this alleged infringement, the filing of an ANDA gives rise to limited consequences. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004). The Federal Circuit has clearly enunciated that, due to that limitation, the mere filing of an ANDA cannot form the basis of a willful infringement finding, *ibid.*, and has warned that a "trial court need not . . . elevate[] the ANDA certification into a finding of willful infringement[,]" *Yamanouchi*, *supra*, 231 F.3d at 1347. Heeding that warning, and considering the nature of the claims brought under the Hatch-Waxman Act, district courts continually dismiss willful infringement claims based solely on the filing of an ANDA and relevant paragraph IV certifications.[1] *See, e.g.*, *Celgene*, *supra*, 412 F. Supp. 2d at 445 (holding that "there can be no

[1] The Court recognizes that, despite the clarity of the Federal Circuit's opinions in *Glaxo*, *supra*, and *Yamanouchi*, *supra*, plaintiffs in Hatch-Waxman Act cases repeatedly allege willful infringement based only on the filing of an ANDA and paragraph IV certification—and district

'willful infringement' where, in cases such as this, the allegedly infringing conduct is limited to the highly technical act of infringement sufficient to confer jurisdiction under the Hatch-Waxman Act"). Indeed, this jurisdiction has never sustained a willful infringement claim brought under 35 U.S.C. § 271(e)(2), and the Court adopts the observations made by a district court in the Eastern District of Virginia:

> [T]he Court is compelled to observe that, given its understanding of the ANDA scheme, excluding allegations of willful infringement based solely on the filing of a baseless ANDA application serves the purposes of the scheme itself, which is clearly to encourage generic companies to participate in the ANDA process so that consumers may benefit from the faster availability of generic drugs. Ultimately, any generic company who loses its patent infringement suit after filing a paragraph IV certification has filed a 'baseless' ANDA application. Indeed, it appears to this Court that its entire inquiry in this case will be grounded on the ANDA and whether or not Defendants are correct that the patent is invalid and/or will not be infringed. Thus it comes as no surprise to this Court that *Glaxo* restricts willful infringement claims supported solely by allegations of baseless ANDA applications. While this is so, generic companies may not file baseless ANDA applications with impunity. The *Glaxo* court is at pains to point out that particularly egregious conduct surrounding the filing of the ANDA and in the litigation itself could warrant attorneys fees as an exceptional case[.]

Aventis Pharma Deutschland GMBH v. Lupin Ltd., 409 F. Supp. 2d 722, 730 (E.D. Va. 2006).

Applying that rationale here, the Court holds that, construing as true all the allegations in the Complaint, Plaintiffs cannot sustain their willful infringement claim against Defendants to

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courts are repeatedly flooded with motions such as the one presented here. *See, e.g.*, *Forest Lab., Inc. v. Ivax Pharm., Inc.*, 2007 WL 788897 (D. Del. Mar. 15, 2007); *Wyeth v. Ranbaxy Lab. Ltd.*, 448 F. Supp. 2d 607 (D.N.J. 2006); *Celgene*, *supra*; *Boehringer Ingelheim Int'l GMBH v. Barr Lab., Inc.*, 2006 WL 1876918 (D. Del. July 6, 2006); *Item Dev. AB v. Sicor Inc.*, 2006 WL 891032 (D. Del. Mar. 31, 2006); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 409 F. Supp. 2d 722 (E.D. Va. 2006); *UCB Societe Anonyme v. Mylan Lab., Inc.*, 2006 WL 486895 (N.D. Ga. Feb. 28, 2006); *Aventis Pharma Deutschland GMBH v. Cbalt Pharm., Inc.*, 355 F. Supp. 2d 586 (D. Mass. 2005). Faced with this recurring issue, the Court's Opinion now joins the litany of literature attempting to inform plaintiffs that the mere filing of an ANDA cannot give rise to a claim of willful infringement.

the extent that it is based solely on Defendants' filing ANDA No. 78-189 and paragraph IV certifications relating to the '559 patent. Indeed, "the artificial and highly technical nature of [Defendants'] 'infringement' does not rise to the level of a literal act of patent infringement that could give rise to a finding of 'willful infringement[.]'" *Celgene*, *supra*, 412 F. Supp. 2d at 445. Therefore, to the extent that paragraph 35 of Plaintiffs' Complaint—which raises the willful infringement claim—relies solely on its paragraph 32 allegation of infringement based on the filing of the ANDA and paragraph IV certifications, the Court dismisses Plaintiffs' willful infringement claim.

Nevertheless, the Court notes that its preclusion of Plaintiffs' willful infringement allegation does not prevent Plaintiffs from seeking an "award attorneys fees under section 285" if they later successfully argue the present case is "exceptional[.]" 35 U.S.C. §§ 271(e)(4), 285. Plaintiffs, in their Complaint, ask the Court to find "that this is an exceptional case, and . . . award . . . attorneys' fees in this action pursuant to 35 U.S.C. § 285[.]" (Cmplt. ¶ E). "Exceptional cases" may arise where a court finds "inequitable conduct before the [United States Patent and Trademark Office], litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement." *Glaxo*, *supra*, 376 F.3d at 1350. The analysis required for a finding that a case is "exceptional" is distinct and separate from the issue of whether a plaintiff may allege a willful infringement claim in its complaint; and it is this distinction that plaintiffs in Hatch-Waxman Act cases overlook in alleging a willful infringement claim based solely on the filing of an ANDA. Nevertheless, as repeated by numerous jurisdictions, in neither instance can "the mere fact that a company has filed an ANDA application or certification . . . support a finding of willful infringement[.]" *Id.* at 1350-51.

Thus, Plaintiffs may still explore on a full record circumstances beyond Defendants' filing of the ANDA and paragraph IV certifications that might justify a finding of willful infringement for purposes of seeking attorneys' fees pursuant to 35 U.S.C. § 285.

III. CONCLUSION

For the reasons expressed above, the Court grants Defendants' motion on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) and dismisses Plaintiffs' allegation of a willful infringement claim set forth in paragraph 35 of the Complaint. Because the Court grants Defendants' motion pursuant to Rule 12(c), Defendants' alternative motion to bifurcate the willful infringement claim is now moot. An appropriate order accompanies this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: February 4, 2008